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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,533	03/08/2002	Alfred Jann	112843-035	5939

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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,533	JANN ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.A.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example in the omission of units regarding the "high molecular weight dextran" in the specification and claims. No new matter may be added.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/05 has been entered.

Claims 6 and 23-24 are being considered on the merits.

Claims 1-5 and 7-21 are withdrawn from consideration as directed to a non-elected invention.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The attempt to incorporate subject matter into this application by reference to Roberfroid *et al.* is ineffective because mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 23-24 are vague, indefinite and confusing in that the nature of the "insulin sensitivity" is not clearly set forth in the instant context. Is this a method of treatment of a medical condition or merely an optional improvement in insulin sensitivity? Moreover, the extent of "increase" of "insulin sensitivity" is not set forth with any particularity. Is it 0.0001%, 0.1%, 1%, 10%, 50%?. No clear indication in this regard is found in the instant specification, particularly with respect to effects or effectiveness of oral administration as now claimed.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant appears to discount the preamble of the claim as insignificant. In the instant case, however, the preamble is deemed to breathe life and meaning into the claim to the extent that the method is directed to a method for "increasing insulin sensitivity in a mammal". One of ordinary skill in the art must be able to determine how the method is carried out and how the method steps recited in the claim accomplish the purpose set forth in the preamble. In other words, to be complete, a method claim must have a preamble reciting the intended purpose of the method and the body of the claim must recite the steps required to achieve the purpose recited in the preamble.

With regard to clarity and precision, it is noted that there is no clear nexus between the process intended to be performed as outlined in the preamble and the body of the claim. The claim as written is neither clear nor precise.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claim 6 of "orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" for the purpose of increasing insulin sensitivity. The recitation in the specification at page 2, lines 30-33 broadly discloses enteral administration for increasing insulin sensitivity in a mammal, but only mentions a nutritional composition which contains dextran. No indication is provided regarding molecular weight or administration protocol.

Insertion of the limitation "having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus of "enteral administration" which would show possession of the concept of the use of "dextran having a molecular weight above about 500,000 and that is administered enterally in an amount from about 2g per day to about 15g per day" for the purpose of increasing insulin sensitivity. The exemplified use of dextran is oral administration and for a purpose different from the claim designated purpose. Thus, this is not sufficient support for the new genus of "orally administering dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in

an amount from about 2 g per day to about 15 g per day" is considered to be the insertion of new matter for the above reasons.

This recitation differs substantially from the invention as disclosed.

Therefore, this material constitutes new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The theoretical considerations provided by applicant are not deemed to demonstrate that at the time the claimed invention was made that Applicant was in possession of the invention now claimed which requires "orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day" for the purpose of "increasing insulin sensitivity in a mammal" as now claimed.

Therefore the rejection is deemed proper and it is adhered to.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a process of "increasing insulin sensitivity in a mammal" by a process comprising "orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" . However, the written disclosure does not disclose the amount of dextran suitable to be administered orally as claimed.

The only dextran preparations provided are in oral form wherein 3-5 volunteers are provided "Dextran T2000" either as one "acute does of 15 g dextran" or a "chronic dose of 10 g per day". The relationship between this dextran and the dosage provided with the claimed dextran and dosage cannot be readily assessed from the instant record. The type of preparation administered is not set forth with any particularity. The only result monitored was the effect of propionic acid in feces upon oral administration of Dextran T2000. The written disclosure suggests that propionic acid concentration in feces increases upon oral administration of dextran.

However, there is nothing on the record regarding a nexus or correlation between oral administration of the T2000 dextran in the amounts now claimed and any increase in insulin sensitivity. It is noteworthy that oral consumption of dextran T2000 induced no relevant changes of blood formula, investigated blood proteins or blood plasma enzymes. How is "increase in insulin sensitivity" monitored and on whom? The effects of "orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day" are not addressed in the present written disclosure. There is no clear indication on the record regarding the administration protocol, form or dosages required to achieve the touted effect of "increasing insulin sensitivity" for oral administration of dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day" as claimed. Further, there is no indication regarding the length of the treatment period required to achieve any result. In addition, the effects of consumption with other oral preparations, such as food cannot be readily assessed. There is insufficient guidance in the written disclosure regarding the making of suitable oral nutritional compositions as claimed for the desired purpose.

Therefore, the claims fail to comply with the enablement requirement, since the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the specification discloses that propionate is produced by fermentation of dextran and that propionate is a physiological modulator of fat and glucose metabolism. From these two statements, applicant concludes that "the oral administration of dextran provides a convenient and simple way of selectively increasing the production of propionate in the gastro-intestinal tract and beneficially modulates physiologic parameters. Accordingly, administration of dextran provides a method for increasing insulin sensitivity". However, these conclusionary remarks fail to demonstrate how to make and use the claimed invention based on the as filed specification. What is lacking in the as filed specification is

specific guidelines to achieve a significant increase in insulin sensitivity by the material claimed. Example 3 is directed to the "chronic" administration of 10g per day of dextran T2000 for 10 days. The results of the administration of one dose of 15 g of dextran T2000 is not provided. Moreover, all the results show is an increase in the output of propionic acid. There is no information regarding any increase in insulin sensitivity due to the enteral administration of this type of dextran.

No information is found regarding the protocol necessary to achieve an increase in propionate or how the effect on insulin sensitivity, i.e., whether it is increased and how much, by the enteral administration of dextran in an amount of about 2 g to about 15 g per day as claimed.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Alsop *et al.* (EP 0153013)

The claims are directed to a process of increasing insulin sensitivity by orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day.

Alsop *et al.* discloses a process of orally administering a nutritional composition comprising dextran having an average molecular weight of about 500,000 and that is provided in a formulation in an amount of 2.5 g/l which is presumed to be administered once a day. See, e.g., Example 1 bridging paragraph between pages 7 and 8.). Given that the molecular weight of dextran is indicated as an average indicates that at least some of the dextran has a molecular weight that is higher than about 500,000.

The effect of increasing insulin sensitivity is an inherent property of the composition.

Claims 6 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alsop *et al.* (EP 0153013) and Mitsuhashi *et al.*(EP 382355)

The claims are directed to a process of increasing insulin sensitivity by orally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day.

Alsop *et al.* discloses a process of orally administering a nutritional composition comprising dextran having an average molecular weight of about 500,000 and that is provided in a formulation in an amount of 2.5 g/l which is presumed to be administered once a day. See, e.g., Example 1 bridging paragraph between pages 7 and 8.). Given that the molecular weight of dextran is indicated as an average indicates that at least some of the dextran has a molecular weight that is higher than about 500,000.

Mitsuhashi *et al.* disclose a process of administering a composition comprising dextran to mammals for the purpose of promoting the growth of intestinal *Bifidobacterium*. A result of this administration is an increase in insulin sensitivity in the mammal at least to some extent (See, e.g., Examples 9 and 11 and page 5, lines 37-43), since it has as an effect the prevention of diabetes. In addition the reference discloses that the addition of certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides is beneficial to enhance the promotion of *Bifidobacterium* (See, e.g., Abstract), which further enhances the desired effect of increasing insulin sensitivity . The reference also discloses that that the nutritional compositions containing dextran also comprise lipid sources "rich" in unsaturated fatty acids, such as

unsaturated fatty acids *per se,* which are naturally "poor" in saturated fatty acids (See, e.g., page 3, lines 14-16).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Alsop *et al.* of administering dextran by administering compositions comprising dextran to mammals by adding certain oligosaccharides such as fructooligosaccharides and xylooligosaccharides and/or unsaturated fatty acids to the compositions as taught by Mitsuhashi *et al.* for the expected benefits of providing compositions which are more complete nutritionally and which has the effect of increasing the *Bifidobacterium* flora and of preventing diabetes by increasing insulin sensitivity at least to some extent.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651